

FILED

NORTH CAROLINA

RICHMOND COUNTY

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RICHMOND CO. C.S.C.

IN THE GENERAL COURT OF JUSTICE

SUPERIOR COURT DIVISION

File No. 17CVS 1042

CYNTHIA ROYSTER, Individually, Ally

Plaintiff,

vs.

BAXTER HEALTHCARE
CORPORATION,

Defendant.

COMPLAINT

COMES NOW, Plaintiff, Cynthia Royster, individually (hereinafter referred to as "Plaintiff"), by and through her attorneys, hereby complains and alleges against Defendant, Baxter Healthcare Corporation, a Delaware corporation, (hereinafter "Defendant"), as follows:

THE PARTIES

1. Cynthia Royster is, and was at all times relevant hereto, a resident and citizen of Richmond County, North Carolina.
2. Upon information and belief, Defendant is, and was at all times relevant hereto, a corporation incorporated in the State of Delaware, with its principal place of business in the State of Illinois, and authorized to do business in the State of North Carolina and was doing business at all times relevant hereto in Richmond County, North Carolina.
3. The true names and capacities, whether individual, corporate, associate, or otherwise, of Defendant, including without limitation, any employer, franchisor, or owner d/b/a thereof, not currently known and therefore not yet named herein, are unknown to Plaintiff, who therefore sues said Defendants by such fictitious names. Plaintiff is informed and believes, and therefore alleges, that Defendants are responsible in some manner for the events and occurrences referred to in this Complaint, and/or owes money

to Plaintiff. Plaintiff will ask leave of the Court to amend this Complaint and insert the true names and capacities of Defendants when the same have been ascertained and to join said Defendants in this action.

4. The underlying acts giving rise to the subject matter of this Complaint occurred in Richmond County, North Carolina and caused injury to person and property in the State of North Carolina.

JURISDICTION AND VENUE

5. Plaintiff incorporates the preceding paragraphs of this Complaint as though said paragraphs were fully set forth at this point herein.
6. Venue is proper in this district because Plaintiff is a resident of Richmond County as required by N.C. Gen. Stat. § 1-82.
7. This action is asserted against Defendant who has engaged in substantial activity within this State with regards to this matter and purposely availed themselves of the laws and protections of the State of North Carolina and the subject matter of this Complaint arises out of acts or omissions within this State by Defendant and thus jurisdiction is properly before this court pursuant to N.C. Gen. Stat. §§ 1-75.4(1)(d) and 1-75.4(3).

GENERAL ALLEGATIONS

8. Plaintiff incorporates the preceding paragraphs of this Complaint as though said paragraphs were fully set forth at this point herein.
9. Plaintiff suffers from end stage renal disease and undergoes peritoneal dialysis treatment as prescribed by her nephrologist.
10. At the time of the injuries complained of, Plaintiff treated at the Dialysis Care of Moore County, a facility operated by DaVita Inc.

11. Prior to November 25, 2014, Plaintiff had no adverse skin reactions to any dialysate used to treat her end stage renal disease.
12. On or about November 25, 2014, Plaintiff's dialysate changed to Extraneal, a brand name of icodextrin peritoneal dialysis solution owned and manufactured by Defendant.
13. Plaintiff had not changed any other medication within the last two months.
14. Plaintiff treated with Extraneal manufactured by Defendant until December 9, 2014.
15. On or about December 6, 2014, Plaintiff began experiencing pain, a rash, and skin peeling under both breasts.
16. On or about December 7, 2014, Plaintiff noticed a rash and pain in her perineal area.
17. On or about December 8, 2014, Plaintiff's rash and pain spread to her abdomen.
18. On or about December 9, 2014 Plaintiff presented to her primary care provider with a rash under her breasts.
19. Plaintiff's primary care provider determined Plaintiff needed to be evaluated at the emergency room.
20. Plaintiff was admitted to Moore Regional Hospital in Pinehurst, NC on December 9, 2014.
21. A biopsy of Plaintiff's skin at Moore Regional Hospital indicated an erythrodermic drug eruption to her dialysate Extraneal.
22. As a result of the drug eruption caused by Extraneal, Plaintiff underwent multiple surgeries and both legs were amputated.
23. Upon information and belief, Defendant designed, manufactured, marketed, sold, and distributed Extraneal.

24. Upon information and belief, Defendant failed to maintain sterile conditions during the manufacture, packaging, distribution, and/or sale of the Extraneal used by Plaintiff.
25. Upon information and belief, Defendant failed to properly clean or maintain a sterile environment for the production, packaging, and/or distribution of the Extraneal used by Plaintiff.
26. Upon information or belief, Defendant failed to properly warn healthcare providers, prospective patients, and/or current patients of the danger associated with the Extraneal used by Plaintiff.
27. At all times relevant hereto, Plaintiff acted in a prudent and reasonable manner and in no way contributed to her injury.
28. As a direct and proximate result of Defendant's acts and/or omission, Plaintiff suffered an extreme reaction to Defendant's product.
29. As a direct and proximate result of the negligence of Defendant, Plaintiff suffered serious, substantial, and permanent injury to her person including, but not limited to, amputation to both legs above the knee.
30. Solely as a result of the aforementioned injuries, Plaintiff has been forced to incur substantial medical expenses, and has suffered mental anguish, pain, suffering, loss of well-being, loss of enjoyment of life, and other serious and permanent injury.

FIRST CAUSE OF ACTION
(Negligence)

31. Plaintiff repeats and realleges the allegations contained in the preceding paragraphs of this complaint as though said paragraphs were fully set forth herein.
32. At all times relevant to this action, Defendants had a duty to exercise reasonable care, and to comply with the existing standards of care, in their preparation, design, research,

development, manufacture, inspection, labeling, marketing, promotion and sale Extraneal; which Defendants introduced into the stream of commerce, including a duty to ensure that users would not suffer from unreasonable, dangerous or untoward adverse side effects.

33. At all times relevant to this action, Defendants had a duty to warn all health care providers and consumers of the risks, dangers, and adverse side effects of Extraneal.
34. At all times relevant to this action Defendant had a duty to maintain their manufacturing facilities in a clean and hygienic manner and failed to do so.
35. At all times relevant to this action, Defendants knew or reasonably should have known that the Extraneal relevant to this action was unreasonably dangerous and defective when used as manufactured.
36. Plaintiff did not contribute in any way to her injuries and has taken all reasonable steps to mitigate their damages.
37. Plaintiff's injuries are a direct and proximate result of Defendant's acts and/or omissions, by and through its employees.
38. Plaintiff is entitled to general, special, incidental and consequential damages as Plaintiff incurred medical, hospital, and future medical treatment as a result of Defendant's acts, by and through its employees.
39. Plaintiff is further entitled to general, special, incidental and consequential damages as Plaintiff suffers from mental anguish, pain, suffering, loss of well-being, loss of enjoyment of life, lost wages, and other serious and permanent injuries as a result of Defendant's acts, by and through its employees.

WHEREFORE, Plaintiff prays for judgment against the above-named Defendant as follows:

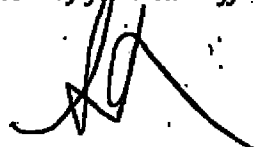
1. For damages in an amount in such sums as shall be determined to fully and fairly compensate Plaintiff for all general, special, incidental, and consequential damages incurred or to be incurred, as the direct and proximate result of the acts of the Defendant, in an amount in excess of TWENTY-FIVE THOUSAND DOLLARS (\$25,000.00);
2. For interest at the statutory rate;
3. Demands a trial by jury; and

For such other and further relief as the Court deems just and proper.

DATED this 17 day of November, 2017.



Joel G. Bowden
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Attorney for Plaintiff



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NORTH CAROLINA
RICHMOND COUNTY

IN THE GENERAL COURT OF JUSTICE
SUPERIOR COURT DIVISION
File No. 17CV31042

CYNTHIA ROYSTER, Individually,

Plaintiff,

vs.

BAXTER HEALTHCARE
CORPORATION,

Defendant.

**PLAINTIFF'S FIRST SET OF
INTERROGATORIES AND REQUESTS
FOR PRODUCTION TO DEFENDANT**

The Plaintiff hereby serves upon you the following written interrogatories under the provisions of Rules 26 and 33 of the Rules of Civil Procedure. You are required to answer these interrogatories separately and fully in writing, under oath, and to serve a copy of your answers on the undersigned within the time provided under the Rules of Civil Procedure. These interrogatories shall be deemed to be continuing in nature until the date of trial so as to require supplemental responses as additional information is obtained between the time answers are served and the time of trial as required by Rule 26 of the Rules of Civil Procedure.

DEFINITIONS

The following definitions apply to each of the Interrogatories and Requests for Production of Documents set forth herein and are deemed to be incorporated in each interrogatory and request.

1. The terms "you" or "your" or "Defendant" shall mean the party to whom these discovery requests are directed as well as any and all persons or entities acting on that party's behalf including, without limitation, agents, representatives, attorneys, experts, investigators or other persons who have gathered information concerning the subject matter of this litigation at your request.

2. The term "Plaintiff" shall refer to Plaintiff and any person acting on its behalf including, without limitation, agents, employees, representatives, insurers, or counsel.

3. The terms "person" or "persons" shall mean and include any natural person, corporation, governmental entity, and every other form of legal entity or division thereof.

4. The term "the Accident" shall refer to the alleged accident referred to in the pleadings in this action.

5. The terms "document" or "documents" shall be used in their broadest sense to refer to any and all printed, typed or recorded matter subject to discovery under Rule 33 of the North Carolina Rules of Civil Procedure, whether maintained in paper or electronic form, including all drafts, non-identical copies, and any attachments or appendices thereto. Without limiting the foregoing, the terms "document" or "documents" shall include all letters, agreements, memoranda, notes, reports, correspondence, films, books, facsimile transmissions, summaries, diagrams, ledgers, photographs, sketches, invoices, receipts, audio recordings, electronic correspondence, computer files or records, contracts, affidavits, written statements of witnesses or other persons having knowledge of facts relevant to this action, memorials of personal conversations or interviews, telephone logs, summaries, drafts, notes and other written or printed materials responsive to the specific question.

6. The term "identify", when used with respect to a document, means to state (1) the date of the document or the date it was created or received; (2) the author or originator of the document; (3) the type of document *i.e.*, whether it is a letter, memorandum, report, etc.; (4) the substance of the document; (5) the recipient or addressee of the document, where applicable; (6) the current location and custodian of each copy of the document; and (7) any and all other information necessary to adequately and completely identify the document for purposes of a Request for Production of Documents or Subpoena Duces Tecum.

7. The term "identify", when used with respect to a person, means to state the person's full name and present or last known address or residence, the person's current employer and business address, and the person's home, business, and cellular telephone numbers. If the person is a corporation or other entity, "identify" means to state its full name, the nature of its organization, the state under which it was organized, and the address of its principal place of business. If any of the above information is not available to you, state any other available means of identifying such person.

8. The term "identify", when used with respect to a communication, means the party shall state (1) the person making or generating the communication; (2) all person(s) to whom the communication was made or directed; (3) the medium of the communication; *e.g.* telephone conference, letter, electronic communication, etc.; (4) the date(s) of such communication; and (5) the subject matter of such communication.

9. The term "describe" means to provide fully and with as much detail and specificity as possible the information requested, state any facts or opinions related to such knowledge or information, identify other parties known to you to also possess such knowledge or information, and list any documents evidencing, reflecting or pertaining to the information provided.

INSTRUCTIONS

1. Set forth your answer to each interrogatory separately and fully. Where you believe that a complete answer to a particular interrogatory or request or part thereof is not possible, answer to the extent possible and provide an explanation for your inability to answer further.

2. For each interrogatory, identify all documents to which you referred or relied upon to answer that interrogatory. Wherever the identification of documents is called for in these interrogatories, you may, in lieu of such identification, attach a complete and legible copy of said document to the interrogatory responses and indicate the specific interrogatory question to which the attached document is intended to be responsive.

3. Where you are requested to produce documents or things in response to these discovery requests, you are to produce all documents or things known to you and in your possession, custody, or control, including those documents or things in the possession of your attorneys, agents, employees, or anyone acting on your behalf.

4. In answering these Interrogatories or Requests, furnish such information as is available to you, not merely such information as is of your own knowledge. This means you are to furnish information which is known by, available to or in possession of your employees, representatives, servants or agents, including your attorney (unless privileged) or any agent or investigator for you or your attorney (unless privileged).

5. If you are aware of any document, item, or thing responsive to these discovery requests which once existed but is no longer available, state the reason such document is no longer available and identify any persons having information regarding the document or item's prior existence or its disposition or loss. For any document or item which has been destroyed, identify the date it was destroyed, the person who destroyed it, the reason it was destroyed, and the facts and circumstances under which it was destroyed.

6. Each of these Interrogatories or Requests is deemed to be a continuing Interrogatory or Request, so as to require you to file supplementary answers if you obtain further or different information between the time your answers are served and the time of trial.

7. If you assert a privilege with regard to any interrogatory or request for production of documents, please submit a privilege log to identify any documents alleged to be privileged, and a description of the document and privilege relied upon.

INTERROGATORIES

1. Identify all person(s) who provided information responsive to the questions posed in these discovery requests, including name, address, and telephone number and job title.

RESPONSE:

2. Please identify all sales representatives working for you who called on physicians or hospitals in North Carolina during the past six years, and their supervisors, and their supervisors, on up to the top of the sales or marketing departments. (By sales representatives working for you, the interrogatory seeks the identify not only of sales representatives or "detail" people who were Defendant employees, but also those who Defendant may have hired to sell or detail a icodextrin peritoneal dialysis solution manufactured by Defendant).

RESPONSE:

3. Please identify those persons working for you from 2000 to present who were authorized to act as liaison, or to reach agreements with physicians, surgeons, or hospitals concerning the development, research, or marketing of any icodextrin peritoneal dialysis solution manufactured by Defendant.

RESPONSE:

4. Please identify those persons working for you from 2000 to present who were authorized to arrange for exhibits concerning any icodextrin peritoneal dialysis solution manufactured by Defendant to be scheduled and set up at meetings of healthcare providers, hospital administrators, or other professional organizations.

RESPONSE:

5. Did you ever design or modify the design or engineering of a icodextrin peritoneal dialysis solution manufactured by Defendant? If yes, please identify the date(s) of the design or modification, the person(s) responsible for the design or modification, and a description of any modifications.

RESPONSE:

6. Did you ever own or license a patent on icodextrin peritoneal dialysis solution manufactured by Defendant? If so, please provide the patent number.

RESPONSE:

7. Did you ever own or license a trademark on a icodextrin peritoneal dialysis solution brand name? If so, please provide the trademark.

RESPONSE:

8. List the addresses of your document depositories or any other place where you maintain or have maintained records concerning the manufacturing, distribution, sales, promotion, marketing, and/or any clinical data pertaining to icodextrin peritoneal dialysis solutions manufactured by Defendant for the period of time when you first manufactured icodextrin peritoneal dialysis solutions up through and including the present. If the records have been moved at all during this time, state the reason for the move, and if a clear chain of custody cannot be established, give an explanation.

RESPONSE:

9. Identify the names and state the present and/or last known address of your agents or employees with the most knowledge pertaining to icodextrin peritoneal dialysis solutions and/or the manufacture of icodextrin peritoneal dialysis solutions, who worked for you during the times you manufactured, produced, promoted, formulated, created, designed, sold and/or tested icodextrin peritoneal dialysis solutions, including but not limited to:

(a) Your Product Managers.

- (b) The safety and compliance individuals in charge of reporting adverse reactions and complaints of side effects to the FDA or any other agency, and investigating all adverse reactions and complaints of side effects.
- (c) Your liaisons to the FDA, whether or not part of the regulatory affairs department.
- (d) Your researchers and developers responsible for the design, proper function, and proper manufacture of your icodextrin peritoneal dialysis solutions.
- (e) Your in-house scientific researcher(s) who ever had any responsibility for the safety or effectiveness of your icodextrin peritoneal dialysis solutions.
- (f) Your chief medical officer.
- (g) Your chief information operating ("CIO") officer.
- (h) Your chief regulatory affairs person.
- (i) The employees responsible for creating and updating the directions for use and/or manufacture of icodextrin peritoneal dialysis solutions.

RESPONSE:

10. Please identify the person or person(s) who participated in any manner in the development of Defendant's icodextrin peritoneal dialysis solutions product complaint or adverse event reporting system. For each person identified, please provide the person's name, address, telephone number, job title, job responsibilities, dates of employment, and if they are no longer employed, the date and reason for termination.

RESPONSE:

11. Please identify the date the icodextrin peritoneal dialysis solutions product complaint or adverse event reporting system was created and describe in detail the reason Defendant developed the system.

RESPONSE:

12. Please identify each icodextrin peritoneal dialysis solutions product complaint or adverse event report that Defendant received including the date received and the providers who submitted the Complaint.

RESPONSE:

13. Please describe in detail Defendant's internal adverse event reporting system including but not limited to the person(s) who developed the adverse event reporting system, the person(s) responsible for overseeing the adverse reporting system, the person(s) that are responsible for submitting adverse events to the FDA, and the procedure(s) Defendant follows when it receives an adverse event report whether from a doctor or patient.

RESPONSE:

14. For each icodextrin peritoneal dialysis solution complaint or adverse event report identified in response to Interrogatory No. 13, please describe in detail all steps or actions Defendant took in response including, but not limited to, the identity of the person(s) responsible for responding to the complaint/report, all communications with the surgeon who submitted the complaint/report, and how the complaint/report was resolved.

RESPONSE:

15. Request for Production was served upon your counsel. Please identify all documents requested in the Request for Production which have been destroyed, disposed of or are no longer available, and set forth the present location of the originals or copies thereof.

RESPONSE:

16. Please identify all persons known to Defendant who have personal knowledge of material facts in this matter. For each person identified, please provide a brief description of their knowledge and provide their last known address and telephone number.

RESPONSE:

- 17. Please state whether Defendant has had any communications with the Plaintiff. If so, please provide the date of the communication, who participated in the communication, and a description of the communication.**

RESPONSE:

- 18. Please state whether Defendant (including its actual and/or apparent agents, servants, and/or employees) has had any communications with the Plaintiff's physician or healthcare providers. If so, please provide the date of the communication, who participated in the communication, and a description of the communication.**

RESPONSE:

- 19. Please provide a detailed description of the instructions Defendant and/or its sales representatives provide to treating physicians with respect to use of Defendant's icodextrin peritoneal dialysis solutions including but not limited to the person(s) who developed the instructions, any and all revisions to the instructions including the date of the revisions, and**

how the instructions are communicated to physicians.

RESPONSE:

20. Please state whether Defendant has ever had communications with the FDA regarding the manufacture of icodextrin peritoneal dialysis solutions. If so, please provide the name, address, and phone number of each person who participated in the communication, the date of the communication, and a description of the communication.

RESPONSE:

21. State the nature and extent of all liability insurance coverage of every kind available directly or indirectly to you to pay any judgment awarded in this action, and include the name or names of each insurance company and the applicable limits of liability insurance in effect for each entity and/or occurrence.

(a) If there was more than one policy of insurance applicable in this instance, identify each insurance company as indicated above and state which liability insurance company is the primary insurance carrier and identify any and all self-insurance, secondary, reserve and /or umbrella liability insurance carriers, if any.

(b) Attach a copy of the coverage/declaration sheet from each such liability

insurance company setting forth all the available limits of coverage applicable to this occurrence.

RESPONSE:

REQUESTS FOR PRODUCTION

1. You are requested to provide copies of any and all documents referred to, relied upon, or identified by you in responding to the preceding Interrogatories.

RESPONSE:

2. Any documents which afforded liability insurance coverage for the incident which is the subject matter of the Plaintiff's Complaint.

RESPONSE:

3. Each and every written, printed, or graphic representation, catalogue, statement, circular, manual, brochure, report, advertisement, or other document which was propounded by or on behalf of the defendant and which mentions, describes or otherwise refers to the virtues, qualities, characteristics, capabilities, or capacities of the product.

RESPONSE:

4. All written reports of each person whom you expect to call as an expert witness at trial.

RESPONSE:

5. All documents reviewed by or relied upon by any expert witness you intend to call at trial.

RESPONSE:

6. The most recent resume or curriculum vitae of each expert whom you expect to call as an expert witness at trial.

RESPONSE:

7. All invoices generated by expert witnesses generated for performing all expert witness services to the defendant, including but not limited to, the fees for the medical examination, the records review, the pretrial preparation, any telephone conference, any trial testimony anticipated and any other fee paid by the defendants for expert fees.

RESPONSE:

8. Any document received pursuant to a subpoena request.

RESPONSE:

9. Any documents prepared during the regular course of business as a result of the incident complained of in the Plaintiff's Complaint.

RESPONSE:

10. Copies of any treaties, standards in the industry, legal authority, rule, case, statute, or code, that will be relied upon in the defense of this case.

RESPONSE:

This the 17th day of November, 2017.



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Attorney for Plaintiff

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